

REMARKS / ARGUMENTS

Claims 8, 9, 11, 40-42, 44-46 and 48-52 remain in this application and are under examination. Claims 40, 41, 45 and 50 are amended for proper antecedence. No new matter is added.

I. Rejection of the Claims Under 35 U.S.C. § 103(a) – Watson et al. Nucleic Acids Research 18(17):5299, 1990 ('Watson') in view of US patent 5,776,746 ('Denney') and US patent 6,020,191 ('Scaria')

The Examiner rejects all the claims of record under 35 U.S.C. 103(3) as being unpatentable over Watson in view of Denney and Scaria. Applicants traverse this ground for rejection.

According to the Examiner, Watson discloses the nucleotide sequence of the 60 kDa cysteine-rich outer membrane protein; Denney discloses that the CMV promoter increases the level of transcription of a desired antigen; and Scaria discloses that CMV promoters are advantageous in that they provide longer duration of expression of a transgene.

(a) None of the references suggest the desirability of making the combination

Applicants submit that none of the cited references suggest the desirability of the combination recited in the claims. None of the cited references suggest using a nucleic acid molecule encoding SEQ ID No: 2 operably linked to a promoter functional in a mammalian cell, as a vaccine. There is otherwise no reason for expressing the protein. The Examiner states that Denney and Scaria discloses that the CMV promoter increases transcription and provides longer duration of expression of a coding sequence. From the Examiner's statements, a skilled person would operably links a nucleic acid molecule encoding SEQ ID No: 2 to a promoter functional in a mammalian cell solely to make lots of the protein for a prolonged period. Applicants submit that no one would do that.

(b) There is no reasonable expectation of success

Applicants further submit that even if a skilled person operably links a nucleic acid molecule encoding SEQ ID No: 2 to a promoter functional in a mammalian cell, there is no reasonable expectation of success. Only a few of the 1296 coding sequences of *C. pneumoniae* are useful as vaccines (see the Declaration under 37 CFR § 1.132 of inventor Andrew Murdin, filed on US 10/334,137, and submitted with the response dated February 23, 2004). The Declaration states that, as part of the assignee's *C. pneumoniae* vaccine programme, 36 *C. pneumoniae* ORFs were tested in the *in vivo* mouse model described in Example 3. These ORFs were linked to the CMV promoter and were expressed. The assignee found that only 8 of the 36 ORFs (i.e. 22%) provided a protective effect. The actual proportion of useful sequences is probably even lower than this because the 36 ORFs were pre-selected as possible vaccine candidates.

There is no motivation to link a nucleic acid molecule encoding SEQ ID No: 2 to a promoter functional in a mammalian cell because a skilled person cannot reasonably expect that such a combination would lead to a useful vaccine. The Examiner states that Denney and Scaria discloses that the CMV promoter increases transcription and provides longer duration of expression of a coding sequence. Even if these statements are true, Applicants submit that Denney and Scaria do not provide motivation because no skilled person would make the claimed combination if he does not reasonably expect the protein to be effective as a vaccine antigen. Such expectations are unwarranted because most coding sequences of *C. pneumoniae* do not elicit an immunoprotective response regardless of how much or for how long the protein is expressed.

Withdrawal of the rejection under 35 U.S.C. §103(a) in view of Watson, Denney and Scaria is requested.

II. Concluding Remarks

In view of the above amendments and remarks, reconsideration and favorable action on all pending claims are respectfully requested. If any questions or issues remain, the Examiner is invited to contact the undersigned at the telephone number set forth below so that a prompt disposition of this application can be achieved.

If a fee is required for an extension of time which is not accounted for, such an extension is requested and the U.S.P.T.O. is authorized to withdraw from our Deposit Account Number 19-0741 any fee required.

Respectfully submitted,

Date: July 19, 2004



Michele M. Simkin
Registration No. 34,717

FOLEY & LARDNER LLP
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5109
Telephone: (202) 672-5427
Facsimile: (202) 672-5399